CANCER RESEARCH AND PREVENTION FOUNDATION
www.preventcancer.org

Carolyn R. Aldigé
President and Founder

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HHS Task Force on Drug Importation
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Task Force Members:

I am writing in response to the public docket established to receive comments on issues related to the importation of prescription drugs.

Our organization's mission is the prevention and early detection of cancer through scientific research and education. Our focus is on cancers that can be prevented through lifestyle changes or early detection followed by prompt treatment.

Along with many others in the health care community, we are concerned about the affordability of drugs for individuals and families, in particular those that are uninsured or underinsured. However, in searching for solutions that will allow access to prescription medication, it is essential that we do not weaken the safety and efficacy of the U.S. drug supply or stifle research and innovation.

Chemotherapy drugs are toxic drugs that have to be properly stored, mixed and regulated, and administered by specially trained nurses who give the drugs in combination with supportive care drugs. Even the slightest impropriety in a drug's composition can impact the effectiveness of the treatment and endanger the life of the patient.

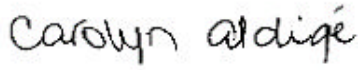
The U.S. system of drug regulation is the world's gold standard, and opening this system to drugs imported from other countries could be catastrophic. Directly, importation could subject patients to drugs that have been altered, weakened, or counterfeited. Drugs may be received by the consumer in different forms, doses or potencies, adding another layer of complexity to the already difficult task of disease management. It is critical that provisions that have been approved by Congress in recent years requiring the Secretary of Health and Human Services (HHS) to certify that reimportation of prescription medications into the United States "poses no additional risk" to health and safety be maintained.

Indirectly, and of equal significance, allowing importation could encourage research and development to outside of the United States. FDA approval is more difficult and may take substantially longer than obtaining approval in another country, and if products not approved by FDA can enter the U.S. market legally, there would be an extremely strong incentive to seek approval where it can be obtained with greater ease.

Finally, if importation is allowed only for FDA approved products, we are concerned about the impact on research and development and the investment in newer and better treatments, or preventive agents, for people with cancer. Importation will provide a disincentive for investment in biomedical research.

CRPF would urge the committee to oppose attempts to weaken the current drug importation laws, and thanks you for your consideration of our concerns.

Sincerely,



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